

MAR - 6 1997

K970459

## 510(k) Summary

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- Introduction** According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.
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- 1. Submitter name, address, contact** Boehringer Mannheim Corporation  
2400 Bisso Lane  
Concord, CA 94524-4117  
(510) 827 - 8215  
Fax number: (510) 687-1850
- Contact Person: Patricia Klimley
- Date Prepared: January 29, 1997
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- 2. Device Name** Proprietary name: Elecsys® CalCheck™ AFP  
Common name: Calibration Verification Material  
Classification name: Single (specified) analyte controls (assayed + unassayed)
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- 3. Predicate device** The Elecsys® CalCheck™ AFP is substantially equivalent to the currently marketed Elecsys® CalCheck™ CEA (K963147).
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- 4. Device Description** The Elecsys® CalCheck™ AFP is a three level single analyte set of lyophilized, human based materials. After reconstitution, they are assayed in triplicate and the results compared to the target values.
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## 510(k) Summary, Continued

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**5. Intended use** The Boehringer Mannheim Elecsys CalCheck AFP is used to verify the calibration assignment for the Boehringer Mannheim Elecsys AFP assay.

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**6. Comparison to predicate device** The Elecsys® CalCheck™ AFP is substantially equivalent to the currently marketed Elecsys® CalCheck™ TSH (K963147).

The following table compares the Elecsys® CalCheck™ AFP with the predicate devices, Elecsys® CalCheck™ TSH. Specific data on the performance of the test have been incorporated into the draft labeling in attachment 5. Labeling for the predicate devices is provided in attachment 6.

**Similarities:**

- Configuration: 3 CalCheck levels: low, mid, and high
- Intended use: To verify calibration

**Differences:**

Feature	CalCheck AFP	CalCheck TSH
Matrix type	Human serum	Horse serum
Analyte	AFP	TSH

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## **510(k) Summary, Continued**

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**6.  
Comparison  
to predicate  
device, (cont.)**

**Performance Characteristics:**

- Value assignment and stability
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